DEC 2 3 2005

K051472

Section O. Biophen LMWH and UFH Control Plasma

(Summary of Safety and Effectiveness)

Submitted by:

Hyphen BioMed
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Contact Person:

Dr. Jean Amiral, President &Scientific Director
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Summary prepared by:

15th April 2005

Name of the device:

Biophen LMWH Control
Biophen LMWH Control Low
&
Biophen UFH Control

Classification Name:

Plasma Coagulation Control

Classification: Class II

Regulation#: 864.5425, for Biophen LMWH & LMWH Low Control Plasma
864.5425 for Biophen UFH control plasma

Product Code: GGN for Biophen LMWH & LMWH Low Control Plasma
GGN for Biophen UFH Control Plasma

Predicate Device Information:

Biophen LMWH & LMWH Low Control Plasma: Control Plasma LMW Heparin (K030965)
Biophen UFH Control Plasma: Heparin Control (K943520) – Ami Bioproducts

Description of the Device/intended use:

Biophen LMWH, LMWH Low and UFH Control Plasma is an in vitro diagnostic quality control intended for use with chromogenic assays to assess precision and accuracy at Heparin low and high levels (in the usual recommended therapeutic range).

Statement of how the technological Characteristics of the device compare to the Predicate device:

Biophen LMWH control uses the same principle as the predicate device Control Plasma LMW Heparin and is substantially equivalent in performance, intended use and safety and effectiveness.

Biophen UFH control uses the same principle as the predicate device Heparin Control and is substantially equivalent in performance, intended use and safety and effectiveness.

Summary of Performance data:

A reproducibility results for the Biophen LMWH, LMWH low and UFH Control plasma is given below:

Biophen LMWH Control	LMWH Concentration (IU/ml)	Acceptable Range (IU/ml)	N	SD
Level 3	0.79	0.69 -0.89	69	0.03
Level 4	1.25	1.10-1.40	69	0.05

Biophen LMWH Control Low	LMWH Low Concentration (IU/ml)	Acceptable Range (IU/ml)	N	SD
Level I	0.25	0.17-0.33	43	0.02
Level II	0.50	0.40-0.60	43	0.03

Biophen UFH Control	UFH Concentration (IU/ml)	Acceptable Range (IU/ml)	N	SD
Level 1	0.21	0.11-0.31	30	0.01
Level 2	0.51	0.36-0.66	30	0.02

(Summary of Safety and Effectiveness)

Submitted by:

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US Agent :

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Phone number : (513) 770-1993
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Summary prepared by:

3rd November 2005

Name of the device:

Biophen Heparin Calibrator
Biophen UFH Calibrator

Classification Name:

Calibrator, Secondary

Classification:

Class II

Regulation#: 862.1150

Product Code: JIT

Predicate Device Information:
K030964 Calibration Plasma LMW Heparin
K042941 Heparin Calibrators & Controls

Device intended use:

Biophen Heparin Calibrator is a set of calibration plasmas for Heparin (UFH and LMWH) measurements, using anti-Xa colorimetric assays (BIOPHEN HEPARIN 3 and 6).
Biophen Heparin Calibrator allows calibrating the assays of Low Molecular Weight Heparin (LMWH) using chromogenic anti-Xa methods. It can be also used for calibrating the measurements of Unfractionated Heparin (UFH) when the BIOPHEN Heparin kit is used.
Biophen heparin is a chromogenic anti-Xa method developed for measuring homogeneously heparin (UFH) and Low Molecular Weight Heparin (LMWH), using the same calibration curve.

BIOPHEN UFH Calibrator is a set of calibration plasmas for Unfractionated Heparin (UFH) measurements, using anti-Xa colorimetric assays (BIOPHEN HEPARIN 3 and 6).
BIOPHEN UFH Calibrator allows calibrating the measurements of Unfractionated Heparin (UFH) when the BIOPHEN Heparin kit is used.

Performance of the Device:

The concentration of the calibrators is determined from the multiple determinations. The following tables show good reproducibility for the LMWH calibrator and UFH calibrator.

Calibrator	Concentration in LMWH (IU/ml)	Intra Assay N	Intra Assay CV	Inter Assay N	Inter Assay SD
Calibrator 1	0	10	NA	50	0.01
Calibrator 2	0.38	10	2.3	50	0.02
Calibrator 3	0.77	10	0.5	50	0.03
Calibrator 4	1.14	10	1.0	50	0.05
Calibrator 5	1.5	10	0.5	50	0.06

Calibrator	Concentration in Unfractionated Heparin (IU/ml)	Intra Assay N	Intra Assay CV	Inter Assay N	Inter Assay SD
Calibrator 1	0	10	NA	28	0
Calibrator 2	0.36	10	1.4	28	0.02
Calibrator 3	0.74	10	1.0	28	0.04
Calibrator 4	1.08	10	0.5	28	0.06
Calibrator 5	1.42	10	0.5	28	0.08

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

HYPHEN Biomed
c/o Mr. Ola Anderson
President
Aniara Corporation
6560 Gove Court
Mason, Ohio 45040

DEC 2 3 2005

Re: k051472
Trade/Device Name: Biophen Low Molecular Weight Heparin (LMWH) Control Plasma
Biophen Low Molecular Weight Heparin (LMWH) Control Low
Biophen Unfractionated Heparin (UFH) Control Plasma
Biophen Heparin Calibrator and Biophen UFH Calibrator
Regulation Number: 21 CFR § 864.5425
Regulation Name: Multipurpose system for in vitro coagulation studies
Regulatory Class: II
Product Code: GGN, GGC, KFF
Dated: November 3, 2005
Received: November 8, 2005

Dear Ms. Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Section D. Statement of Indication for Use

Indications for Use

510(k) Number (if known): K051472

Device Name: Biophen Low Molecular Weight Heparin (LMWH) Control Plasma,

Biophen Low Molecular Weight Heparin (LMWH) Control Low,

& Biophen Unfractionated Heparin (UFH) Control Plasma

Indications for Use:

Biophen Low Molecular Weight Heparin (LMWH), Low Molecular Weight Heparin Low (LMWH Low) and Unfractionated Heparin (UFH) control are set of control plasmas for the quality control of Low Molecular weight Heparin(LMWH) and Unfractionated Heparin(UFH) measurements using anti Xa colorimetric assays (Biophen Heparin 3 & 6) .

These control plasmas are within the usual therapeutic range recommended for the low molecular weight heparin (LMWH) and Unfractionated Heparin (UFH).

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K051472

Section E. Statement of Indication for Use

Indications for Use

510(k) Number (if known): K051472

Device Name: Biophen Heparin Calibrator &

Biophen UFH calibrator

Indications for Use:

Biophen Heparin & Unfractionated heparin (UFH) Calibrators are set of calibration plasmas for the measurement of Low molecular weight heparin (LMWH) and Unfractionated heparin, using anti-Xa colorimetric assays.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K051472